PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Lee, Won-Hee

8th Fl., Sung-ji Heights II, 642-16 Yoksam-dong, Kangnam-ku, Seoul 135-080, Republic of Korea

PCT

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 59.3(e) and 61.1(b), first sentence and Administrative Instructions, Section 601(a))

Date of mailing *(day/month/year)*	13 APRIL 2004 (13.04.2004)
Applicant's or agent's file reference: 3FPO-08-04	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2003/001951	24 SEPTEMBER 2003 (24.09.2003)	27 SEPTEMBER 2002 (27.09.2002)

Applicant

Genexine Inc. et al

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

07 APRIL 2004 (07.04.2004)

2. This date of receipt is :

[X] the actual date of receipt of the demand by this Authority (Rule 61.1(b)).

[ ] the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).

[ ] the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. [ ] **ATTENTION**: That date of receipt is **after** the expiration of 19 months from the priority date. Consequently, in respect of some Offices, the demand does not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)) and the acts for entry into the national phase must therefore be performed within 20 months from the priority date (or later in some Offices). **However**, in respect of some other Offices, the time limit of 30 months (or later) may nevertheless apply. See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

[ ] *(If applicable)* This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/KR	Authorized officer
Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea	COMMISSIONER
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-5207

Form PCT/IPEA/402 (April 2002; reprint January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING

To:
Lee, Won-Hee

8th Fl., Sung-ji Heights II, 642-16 Yoksam-dong, Kangnam-ku,
Seoul 135-080, Republic of Korea

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	19 JANUARY 2005 (19.01.2005)
Applicant's or agent's file reference 3FPO-08-04	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/months/year)*
PCT/KR2003/001951	**24 SEPTEMBER 2003 (24.09.2003)**	27 SEPTEMBER 2002 (27.09.2002)

Applicant

Genexine Inc. et al

1. The applicant is hereby notified that International Preliminary Examining Authority transmits here with the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report(but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details in the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/KR	Authorized officer
Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea	COMMISSIONER
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-5131

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference 3FPO-08-04	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/001951**	International filing date *(day/month/year)* **24 SEPTEMBER 2003 (24.09.2003)**	Priority date *(day/month/year)* 27 SEPTEMBER 2002 (27.09.2002)

International Patent Classification (IPC) or national classification and IPC

IPC7 A61K 39/29

Applicant

Genexine Inc. et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
07 APRIL 2004 (07.04.2004)	17 JANUARY 2005 (17.01.2005)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LIM, Hea Joon Telephone No. 82-42-481-5600

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/001951

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[ ] the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

[ ] the claims:
pages _____ , as originally filed
pages _____ , as amended (together with any statment) under Article 19
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

[ ] the drawings:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

[ ] the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[X] the language of publication of the international application(under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/ or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained inthe international application in written form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form

[X] The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.

[X] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:
[ ] the description, pages _____
[ ] the claims, Nos. _____
[ ] the drawings, sheets _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION

International aplication No.
PCT/KR2003/001951

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15, 16-29, 30-33, 34-37	YES
	Claims		NO
Inventive step (IS)	Claims	1-15, 16-29, 30-33, 34-37	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-15, 16-29, 30-33, 34-37	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1) The following document have been considered for the purpose of this report:
D1=J Gen Virol., 2002 Feb, vol.83(Pt2), p369-81
D2=J Gen Virol., 2001 Feb, vol.82(Pt6), p1299-308

2) Novelty

Claims 1-15, 16-29, 30-33, 34-37 relate to a vaccine enhancing the protective immunity to Hepatitis C virus using plasmid DNA and recombinant adenovirus, more particularly to a vaccine consisting of core E1-E2 expressing DNA vaccine, nonstructural protein NS3 and NS4 expressing DNA vaccine.

D1 and D2 discloses nonstructural protein NS3 expressing DNA vaccine contained in eukaryotic expression vector, which is different from this invention in terms of vector and element of HCV.

Since claims 1-15, 16-29, 30-33, 34-37 in this invention discloses E1-E2, deletion of E1-E2, NS3 and NS4 for antigen, different from amylase in document D1, those claims are considered to be novel.

3) Inventive Step

Claims 1-15, 16-29, 30-33, 34-37 disclosed the E1-E2 expressing DNA vaccine containing deletion in E1-E2 element and NS3 and NS4 expressing vaccine, whereas D1 and D2 reported the effect of NS3 and NS4 expression for immunity. Furthermore this invention utilized adenovirus system enabled DNA priming-recombinant adenovirus boosting method which enhances the Th1 immune response for more effective cellular immunity, whereas D1 and D2 utilized the regular eukaryotic expression vector. The effective induction of cellular immune response caused by the recombinant vaccine in this invention is confirmed to protect recipient against HCV infection in chimpanzee model resembled in human most.

Therefore, claims 1-15, 16-29, 30-33, 34-37 in this invention appear to involve an inventive step,

4) Industrial applicability

The subject matter of claims 1-15, 16-29, 30-33, 34-37 is considered to be industrially applicable.